Managing Partner Suzy Im said, "We are driving the DAC (Digitalization, Automation, Cross-industry collaboration) movement by leading with 'MASS' solutions for S. Korean companies, shifting from a technology-driven to a market-driven approach to shift the paradigm to a proactive one."

The Path K-Innovation Must Take: Apply One Approach to Address Two Goals – Regulatory & Market Approval

What are the necessary conditions for S. Korean innovative companies to succeed in the U.S. market? Some might point to "technology," but Suzy Im, Managing Partner of BDMT Global, emphasized the need to shift the paradigm from "technology-driven" to "market-driven."

S. Korean innovative technologies are making their mark on the global stage. Beyond K-pop, there are growing expectations that K-tech and K-shipbuilding will shake up the global industrial landscape. However, conquering the U.S. market, the world's largest market, is not easy with technology alone.

Fortune Korea met with a figure who is at the forefront of advanced technology and the medical industry, helping companies enter the U.S. market. This is Suzy Im, Managing Partner of BDMT Global in Boston and a Marketing Professor at Emerson College.

For the past 20 years, Im has led the growth of numerous technology companies in the U.S. A business growth and commercialization innovation leader with numerous awards, and an architect of market-entry ecosystems, Im's ongoing mission is clear: to successfully guide innovative companies into the U.S. market by shifting the paradigm from "technology-driven" to "market-driven."

To realize this paradigm shift, BDMT Global, led by Im, has been spearheading the DAC movement since 2021, which stands for Digitization, Automation, and Cross-Industry Collaboration. In addition, we are expanding the MASS (Market Approval Starter-Scaler) solutions to support S. Korean companies in effectively conveying the "impact" of their technology to the local market. BDMT's activities have already gained the trust of prestigious local institutions, with Mayo Clinic Laboratories participating as a sponsor in 2023.

Fortune Korea: So, what should Korean healthcare companies do first to expand in the U.S.?

Suzy Im: You have to apply one approach to address two goals together - FDA approval and market approval.

Fortune Korea: You emphasized that companies must simultaneously achieve FDA approval and market approval. What is the reason for this?

Suzy Im: Having worked in this field for over 20 years, I have directly experienced the successes and failures of numerous companies on the front lines. One of the core reasons why companies with sufficient technology fail to achieve successful commercialization in the U.S. market is that they only focus on regulatory approval.

Fortune Korea: FDA approval seems like an important gateway.

Suzy Im: That's right. However, FDA approval grants the technical and legal right to use the product safely and effectively, but it doesn't actually give you the ability to sell the product. It's about the safety and effectiveness of the technology.

"It's not a matter of quality, but of market acceptance. If you change the question from 'Should we go?' to 'How?', you'll see the right approach."

Even if you prove it, without trust and demand from hospitals, insurance companies, and procurement, there will be no sales. This ability must be built through a market approval process that builds market trust, awareness, and acceptance.

Fortune Korea: So why are we so obsessed with approval?

Suzy Im: Most startup founders are R&D-based, so they know the technology very well. However, they don't even know what they don't know about the distribution market. If they wait for FDA approval and miss the market entry window, the technology may no longer be innovative. FDA approval is also challenging.

Fortune Korea: Isn't that why we're pouring resources into this?

Suzy Im: FDA approval is, of course, difficult, and it's often delayed for unforeseen reasons. That's precisely why market approval efforts are so crucial. If a company has secured market approval in advance through community partnerships and educational campaigns, a delay in FDA approval isn't fatal. Rather, it becomes manageable. Partners can remain engaged, the community can stay informed, and the brand can continue to build trust.

Fortune Korea: Is market approval limited to biohealth?

Suzy Im: No. It applies to all companies aiming to enter the U.S. market, including the technology market. Successful market expansion and long-term success are difficult with simple sales approaches. A winning platform based on technological prowess and innovation is essential.

The key strategy is to secure market approval before market entry through KOL (Key Opinion Leader) strategies, building relationships with technology analysts (tech influencers), and with market leaders. This is something we've learned from past experience. When global companies (such as Siemens, Teradyne, and Samsung's IT business) entered the U.S. market, I led the AR (Analyst Relations) team and recognized their tremendous influence over "the deal."

Fortune Korea: Are there any unfortunate examples of domestic companies that received FDA approval but failed in the market?

Suzy Im: It's quite common. I've even witnessed unfortunate cases where mass production was initiated before verifying market demand, leading to inventory piling up in warehouses.

Some companies received FDA approval and went public, but instead of attending "popular exhibitions," they chose academic conferences. After local meetings, I received feedback that "technically, we received FDA approval, but in our current state, the market doesn't need it." Ultimately, it took six months to update the product's features, and that was the problem.

Fortune Korea: We updated it, so why did it become a problem?

Suzy Im: The U.S. market is cautious. Once trust is lost or a first impression is out of touch with market needs, it's extremely difficult to recover. A single bad first impression can be a fatal risk. The market approval process is an essential safeguard to prevent such trial-and-error. If an innovative technology is delayed in its launch, it ceases to be innovative. It's unfortunate that AI companies are increasingly facing sales difficulties due to delayed market launches and negative user feedback, even after receiving FDA approval.

Fortune Korea: On the other hand, are there any examples of simultaneous strategies that have proven successful?

Suzy Im: Korean company Orange Biomed collaborated with key leaders before FDA approval to launch the "M.A.P. Your Health" campaign. We've also accelerated our efforts to support other innovators with this simultaneous strategy with the BDMT Global + MEDevice Boston Innovator Summit, bringing top S. Korean innovators directly to the U.S. market for a key opportunity to engage with local ecosystem players. Attendees evaluated BDMT Global's panel session as the most informative and interesting part of the entire event, and our booth featuring S. Korean innovation received the most visitors.

Managing Partner Suzy Im emphasized that when Korean innovative companies enter the U.S. market, they must pass through the gate of trust, which includes not only FDA approval but also "market approval."

Fortune Korea: What specific achievements did innovative companies gain through the summit?

Suzy Im: S. Korean innovator, elecell, won a product award at the Summit, which was not just a trophy but a powerful market validation tool. Before the award, panelists, many of whom are active startup investors, publicly promoted the product's potential, which increased

interest and trust in the company, leading to the award. This award, based on credibility, became a channel for exposure to investors and potential partners.

Fortune Korea: How can BDMT Global's role help solve S. Korean companies' challenges?

Suzy Im: We act as the strongest and most reliable local partner for innovative technology companies to launch products and grow their company value in the U.S. market. We provide an extensive and rigorously selected local network of investors, top industry leaders, and key decision-makers.

We are not simply a supporting organization; we act as a true internal team for our client companies, performing customized roles. The recently launched MASS solutions to help companies conduct R&D and market testing simultaneously, validating value through local feedback.

It assists startups planning a "flip" (a strategic shift in business model or target market) by linking market validation and flip strategies from the outset, enabling them to quickly build a foundation of trust for funding and growth.

The U.S. market is currently actively seeking and funding solutions to revitalize various industries. The challenge isn't whether to enter the market, but rather possessing the capabilities and expertise to quickly build company value and reputation to successfully enter and expand within the market.